The City of New York

BUREAU FOR RADIATION CONTROL
DEPARTMENT OF HEALTH
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June 16, 1982

TO: Mr. Donald A. Nussbaumer, Assistant Director for State Agreements Programs, Office of State Programs, U. S. Nuclear Regulatory Commission

FROM: Dr. Leonard R. Solon, Director, Bureau for Radiation Control
N. Y. C. Department of Health

SUBJECT: COMMENTS ON PROPOSED REVISION TO PART 35 OF THE CODE OF FEDERAL REGULATIONS (HUMAN USES OF BYPRODUCT MATERIAL)

In response to memorandum dated May 13, 1982 from Mr. Donald A. Nussbaumer, Assistant Director for State Agreements Programs, we offer the following comments to the proposed revision to Part 35 of the Code of Federal Regulations.

The staff of the U. S. Nuclear Regulatory Commission proposes to simplify the licensing process for medical licensees by transferring all requirements for human uses of byproduct material from all sources to 10 CFR Part 35. The NRC also proposes to simplify the current review process by eliminating the requirement that applicants submit to NRC for review, detailed procedures describing how they intend to meet requirements in the regulations.

In addition, the revision of Part 35 would discontinue the issuance of general licenses. The NRC has concluded that the general license leads to unacceptable problems with ability to inspect and it no longer serves a useful role in regulating human uses.

The staff of the Bureau for Radiation Control has reviewed carefully the proposed revision of Part 35. Although the licensing process will be simplified by transferring all requirements for human uses of byproduct material to the regulations, the workload of the inspection staff will be perforce increased. Also, since applicants would no longer submit to the NRC detailed procedures of their program, the applicants can no longer receive prelicensing guidance from the NRC staff. Our own experience is that this guidance is constructive.

It is our opinion that the NRC decision to discontinue issuing general licenses for human use is a prudent one. New York City Department of Health has never issued general licenses for human use, primarily because of the lack

of regulatory control of the activities of the licensees.

We welcome the opportunity to comment on the proposed revision of these regulations. If any further clarification of our observations is required, please let me know.

LRS:Lr

cc: Mr. John Spath, N.Y.S. Energy Office
Dr. Karim Rimawi, N.Y.S. Dept. of Health